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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/046,728 | 01/17/2002 | John Victor Lamont | 111723 | 2576 |

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| EXAMINER |
| FORMAN, BETTY J |

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| ART UNIT | PAPER NUMBER |
| 1634 | |

DATE MAILED: 08/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|---------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/046,728 | LAMONT ET AL. |
| Examiner | Art Unit | |
| BJ Forman | 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 June 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 16 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Restrictions

1. Applicant's election with traverse of Group I in Paper No. 9 is acknowledged. The traversal is on the grounds(s) that it would not be undue burden to examine the claims of all groups I-III because a search for the subject matter of any one group of claims would encompass a search for the subject matter of the remaining claims. However, it is maintained that undue burden would be required to examine the claims of groups II and III along with claims of group I as evidenced by the fact that the claims of groups I, II and III have acquired a separate status in the art as recognized by their different classifications as recognized by their divergent subject matter and because a search of the subject matter of invention I is not co-extensive with a search of inventions II and/or III. Specifically, a search of the subject matter of Group I would encompass a search of arrays, multiple reaction site arrays, reaction site labeling, solid support materials, array-molecule attachments and array-molecule arrangements. A search of the subject matter of Group II would encompass a search of computers, computer hardware components, computer software components and integration between imaging methods and computers. A search of the subject matter of Group III would encompass a search of imaging devices, integration of imaging devices and computers and integration of imaging devices with methods of reaction site detection, reaction site registration and signal measurement. For the reasons stated above, it is maintained that undue burden would be required to examine all of the claims of groups I-III.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-14 are currently under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-14 are indefinite in Claim 1 because the claim is drawn to a method for imaging molecules but the claim does not recite method steps for imaging molecules. Claim 1 recites method steps of imaging the array, detecting molecules, aligning discrete regions and determining the amount of signal, but the claim does not recite steps for imaging the molecules. Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity and make clear what subject matter that claims encompass as well as make clear the subject matter from which others would be precluded, *Ex parte Erlich*, 3 USPQ2d 1011 at 6. It is suggested that Claim 1 be amended to recite positive and active steps for imaging molecules as described in the specification.

b. Claims 1-14 are indefinite in Claim 1 for the recitation "at a known position with respect to the array" because it is unclear whether the "known position" is on the array. It is suggested that Claim 1 be amended to clarify e.g. replace "with respect to" with "on" (page 4, lines 4-19).

c. Claims 1-14 are indefinite in Claim 1 for the recitation "the amount of detectable signal" because "amount" and "detectable signal" both lack proper antecedent basis in the claim. It is suggested that Claim 1 be amended to provide proper antecedent basis e.g. in line 1, after "molecules", insert "comprising detectable labels".

d. Claim 14 is indefinite for the recitation "the image generated in step (i)" because the recitation lacks proper antecedent basis in Claim 1, step (i) which is not drawn to a generated

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image. It is suggested that Claim 1 and/or Claim 14 be amended to provide proper antecedent basis.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1, 2 and 4-10 are rejected under 35 U.S.C. 102(e) as being anticipated by

Noblett (U.S. Patent No. 6,362,004, filed 9 November 1999).

Regarding Claim 1, Noblett discloses a method of imaging molecules contained in an array of discrete reaction sites on the surface of a solid support comprising: imaging the array and detecting a first molecule located on the solid support at a known position (i.e. fiducial mark, Column 5, lines 32-56) by reference to the first molecule aligning inspection windows in registration with the discrete reaction sites (Column 3, lines 32-35) and determining the amount of detectable signal in each window (Column 3, lines 24-35; Column 7, lines 21-67 and Claims 13-16).

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Regarding Claim 2, Noblett discloses the method wherein detection of the first molecule is carried out by aligning a first inspection window within a region of the support that includes the first molecule and searching (scanning) within the window for an image of the first molecule (Column 7, line 21-Column 8, line 4).

Regarding Claim 4, Noblett discloses the method wherein after detecting the first molecule, the first inspection window is repositioned so that one or more reaction sites is located within the window, detecting the one or more sites and by reference to the first molecule, aligning a further inspection window (Column 7, line 61-Column 8, line 4 and Claim 15).

Regarding Claim 5, Noblett discloses the method wherein the array of reaction sites defines a corner within which the first molecule is located (Column 7, line 21-Column 8, line 4 and Fig. 2 & 7).

Regarding Claim 6, Noblett discloses the method further comprising detecting a second molecule (i.e. fiducial) on the solid support located at a known position and aligning the inspection windows by reference to both first and second molecules (Column 7, lines 61-66).

Regarding Claim 7, Noblett discloses the method wherein imagining is carried out by detecting emitted radiation (Column 7, lines 31-43 and Claim 13).

Regarding Claim 8, Noblett discloses the method wherein the radiation is fluorescent (Column 4, lines 35-49 and Claim 13).

Regarding Claim 9, Noblett discloses the method wherein the molecules of the array are capable of reacting with an analyte i.e. genetic material (Column 3, lines 50-53 and Claims 3-4).

Regarding Claim 10, Noblett discloses the method wherein the molecules of the array are polynucleotides i.e. genetic probe material (Column 3, lines 50-53 and Claims 3-4).

6. Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Juncosa et al (U.S. Patent No. 6,309,601 B1, filed 1 May 1997).

Regarding Claim 1, Juncosa et al disclose a method of imaging molecules contained in an array of discrete reaction sites on the surface of a solid support comprising: imaging the array and detecting a first molecule located on the solid support at a known position by reference to the first molecule aligning inspection windows in registration with the discrete reaction sites and determining the amount of detectable signal in each window (Column 4, line 48-Column 5, line 2 and Column 10, line 41-Column 11, line 10).

Regarding Claim 2, Juncosa et al discloses the method wherein detection of the first molecule is carried out by aligning a first inspection window within a region of the support that includes the first molecule and searching within the window for an image of the first molecule (Column 4, line 48-Column 5, line 2 and Column 10, line 41-Column 11, line 10).

Regarding Claim 3, Juncosa et al disclose the method wherein the first inspection window defines a two-dimensional array of pixels and searching is carried out by scanning diagonally the array of pixels and determining values for the pixels (Column 4, line 48-Column 5, line 2 and Column 10, line 41-Column 11, line 10 and Fig. 6A).

Regarding Claim 4, Juncosa et al disclose the method wherein after detecting the first molecule, the first inspection window is repositioned so that one or more reaction sites is located within the window, detecting the one or more sites and by reference to the first molecule, aligning a further inspection window (Column 10, lines 41-60 and Column 12, lines 1-11).

Regarding Claim 5, Juncosa et al disclose the method wherein the array of reaction sites defines a corner within which the first molecule is located (Column 5, lines 38-51 and Fig 1).

Regarding Claim 6, Juncosa et al disclose the method further comprising detecting a second molecule (i.e. markers and/or fiducials) on the solid support located at a known position and aligning the inspection windows by reference to both first and second molecules (Column 11, lines 3-10).

Regarding Claim 7, Juncosa et al disclose the method wherein imagining is carried out by detecting emitted radiation (Column 5, lines 43-48).

Regarding Claim 8, Juncosa et al disclose the method wherein the radiation is fluorescent (Column 5, lines 43-48).

Regarding Claim 9, Juncosa et al disclose the method wherein the molecules of the array are capable of reacting with an analyte (Column 5, lines 43-48).

Regarding Claim 10, Juncosa et al disclose the method wherein the molecules of the array are polynucleotides, proteins, antibodies or organic compounds (Column 5, lines 43-48).

Regarding Claim 11, Juncosa et al disclose the method wherein the solid support is less than 1 cm² (Column 6, lines 21-23).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Juncosa et al (U.S. Patent No. 6,309,601 B1, filed 1 May 1997) in view of Trulson et al (U.S. Patent No. 5,578,832, issued 26 November 1996).

Regarding Claim 12, Juncosa et al teach the method of imaging molecules contained in an array of discrete reaction sites on the surface of a solid support comprising: imaging the array and detecting a first molecule located on the solid support at a known position by reference to the first molecule aligning inspection windows in registration with the discrete reaction sites and determining the amount of detectable signal in each window (Column 4, line 48-Column 5, line 2 and Column 10, line 41-Column 11, line 10) wherein the array comprises a solid support (Column 5, lines 38-41) but they are silent regarding the composition of the solid support. However, arrays on solid support comprising ceramic, glass or silicon were well known in the art at the time the claimed invention was made as taught by Trulson et al. Specifically, Trulson et al teach a similar method of imaging molecules contained in an array of discrete reaction sites on the surface of a solid support comprising: imaging the array and detecting a first molecule located on the solid support at a known position by reference to the and determining the amount of detectable signal in each window (Claims 14-22) wherein the solid support is glass, silicon or ceramic material (Column 4, lines 46-67 and Claim 22). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the routinely practiced glass, silicon or ceramic support of Trulson et al to the support of Juncosa et al based on the facts that they are routinely practiced in the art and are the preferred supports Trulson et al (Column 4, lines 66-67).

Regarding Claim 13, Juncosa et al teach the method wherein the molecules are on the surface of the array (Column 5, lines 38-50) but they are silent regarding covalent attachment to the surface. However, covalent attachment was well known and routinely practiced in the art at the time the claimed invention was made as taught by Trulson et al (Column 4, lines 18-20). It would have been obvious to one of ordinary skill in the art at the time the claimed

invention was made to apply the covalently attached molecules of Trulson et al to the molecules of Juncosa et al and to covalently attach the molecules to thereby provide molecules which would remain stably attached under a wide range of experimental and environmental conditions thereby providing a multi-functional and/ or reusable array of molecules. The skilled practitioner in the art would have desired a multi-functional and/or reusable array for the obvious benefits of economy of manufacture and reagents.

Regarding Claim 14, Juncosa et al teach the method wherein the image generated is measured (Column 11, lines 11-48) but they do not teach the image must be above a pre-defined value. However, Trulson et al teach the similar method wherein the image generated must be above a pre-determined value i.e. peak (Claim 16). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the image generation of Juncosa et al by determining a predetermined peak value of the image as taught by Trulson et al (Claim 16) thereby obtaining the image at its known peak value for the obvious benefits of optimizing signal detection to thereby maximize experimental results.

Conclusion

9. No claim is allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
August 7, 2002